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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	PAPER NUMBER
1634	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,362	GINSBURG ET AL.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-21* is/are pending in the application.

4a) Of the above claim(s) *17-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-16,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The examiner reviewing your application at the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Jehanne Sitton.

DETAILED ACTION

2. Currently, claims 12-21 are pending in the instant application. Claims 17-19 are withdrawn from consideration as being drawn to a non elected invention. This action is written in response to applicant's correspondence submitted 7/9/2008. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. The following rejections are either newly presented, necessitated by amendment, or are reiterated from the previous office action. Any rejections not reiterated in this action have been withdrawn as necessitated by applicant's amendments to the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

3. It is noted that claims 17-19 have not been provided with the proper "Withdrawn" claim status identifier. Any subsequence amendment submission with incorrect status identifiers will result in a "Notice of Non-compliant Amendment".

Specification

4. The amendment filed 8/23/2004 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the preliminary amendment filed 8/23/2004 added SEQ ID NOS to the specification which do not appear to have support in the original

disclosure. No sequence listing was filed with the instant application nor in provisional application 60/448,264. Although the drawings appear to provide support for SEQ ID NO: 1, 2, and 19, and various nucleotide oligomers are set forth in the specification, the sequence listing contains additional sequences which were not submitted with the application at the time of filing. Although table 1 refers to specific SEQ ID NOS, those sequences were not provided with the application at the time of filing. Other than providing a statement that the paper copy and the computer readable form are the same, the response accompanying the amendment filed 8/23/2004 provides no explanation for the specific contents of the sequence listing, nor any statement pertaining to the inclusion of new matter. Applicant is required to cancel the new matter in the reply to this Office Action or to provide detailed explanation regarding support in the originally filed disclosure for each new sequence.

Response to Arguments

5. The response traverses the specification objection and asserts that the Examiner has failed to provide evidence that an ordinary artisan would not recognize that the variants presented in Table 1 are in reference to the wild type sequence and Applicants assert that an artisan of ordinary skill would clearly "interpret Table 1 in view of the wild type nucleic acid and amino acid sequence". The response further points to the Specification at page 94 as evidence for support for the sequence listing. These arguments as well as the specification have been thoroughly reviewed but were not found persuasive. The originally filed specification does not teach which wild type sequence and in some cases, where specifically in the wildtype sequence, the changes are made. The originally filed disclosure supports SEQ ID NOS 1, 2, and 19. However, it is not clear where "149+5G>A" is in SEQ ID NO: 1 or 19, or what the necessary

resulting amino acid sequence would be. Applicants response provides no explanation as to how or why the ordinary artisan would interpret the disclosure in table 1, page 94, coupled with the originally filed sequence, to arrive specifically and only at SEQ ID NOS 5-18. Applicants remarks and explanations at page 7, regarding SEQ ID NOS 29-31 in figure 4B are found persuasive and this ground of objection has been withdrawn.

Claim Rejections - 35 USC § 112

6. Claims 12-16, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection was previously presented in section 4 of the office action mailed 12/29/2006 and is reiterated below.

There are many factors to be considered when determining whether there is sufficient evidence to support determination that a disclosure does not satisfy the enablement requirements and whether any necessary experimentation is undue. These factors have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The rejection is maintained for claims 12-16 and 20, and newly presented for newly added claim 21.

The nature of the invention and the breadth of the claims:

The specification defines the recitation of "MCFD2" as a protein or nucleic acid, that in some mutant forms, is correlated with factor V or factor VIII deficiency (F5F8D) (page 9, lines 20-24). Claims 12-16, and 20-21 are drawn broadly drawn to encompass methods for detecting broadly "any" variant MCFD2 polypeptides in a human subject subject, including any variants which are correlated with or indicative of F5F8D, and diagnosing factor 5 and factor 8 deficiency based on the detection of "any" variant. The claims encompass methods which detect any polypeptide variant or nucleotide variation in the MCFD2 gene which encode a variant MCFD2 polypeptide, including any C-terminal truncation of SEQ ID NO: 2 (claim 13), or "encodes a change in the amino acid sequence of said variant MCFD2 polypeptide" (claim 20), as well as variants which "prevents expression of normal MCFD2 polypeptide" (claim 21). The claims do not define the identity or position of the polypeptide or nucleotide variation.

The invention is in a class of inventions which the CAFC has characterized as 'the unpredictable arts such as chemistry and biology" (Mycolgen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Federal Circuit 2001)).

The amount of direction or guidance and presence and absence of working examples:

The specification at page 1, teaches that F5F8D is associated with bleeding tendency and plasma levels of FV and FVIII in the range of 5-30%. The specification teaches that this disease is autosomal recessive, representing a condition distinct from coinheritance of both FV deficiency (parahemophilia), and FVIII deficiency (classic hemophilia, hemophilia A). The specification teaches that mutations in LMAN1, which encodes the endoplasmic reticulum-Golgi

intermediate compartment type I membrane protein ERGIC-53, account for the majority of patients with F5F8D, but that families with the disease were found who lacked LMAN1 mutations.

The specification teaches the genomic sequence comprising multiple coagulation factor deficiency 2, MCFD2 in humans, (SEQ ID NO: 19), as well as the coding sequence (SEQ ID NO: 1), and the polypeptide (SEQ ID NO: 2). The specification also teaches 7 mutations that were identified in human patients having F5F8D (see Table 1, page 95: 149+5 G>A, 309+1 G>A, 103delC, 249DelT, 263-270delTTGATGGC, C387>G, and T407>C). Although table 1 references specific SEQ ID NO: with regard to the mutations, the position of these mutations in SEQ ID NOS 1, 2, and 19 is unclear.

The specification teaches that 3 of the mutations resulted in frameshift mutations, two mutations were in splice sites, and 2 mutations resulted in amino acid substitutions (D129E and I136T) (page 94). The specification teaches that the two amino acid substitutions were located in a putative EF hand and were excluded as a common sequence polymorphism in a screen of over 200 unaffected chromosomes.

The specification does not teach the specific function of MCFD2, but teaches that the amino acid sequence includes a predicted signal peptide at the N terminus, and two calmodulin-like EF hands for putative Calcium binding at the C-terminus (page 94). The specification teaches that the D129E mutant and I136T mutant displayed diffuse staining patterns in cells as opposed to wildtype MCFD2 which overlapped with LMAN1 (page 97). The specification also teaches that in vitro studies found that MCFD2 interacts with LMAN1 in a calcium dependent manner (page 98). However, other than identifying the specific variants set forth in table 1, the

specification does not teach which additional amino acids in MCFD2 would be expected to be associated with F5F8D, nor how any variants, other than the 2 missense mutations, would be expected to alter the function, expression, or activity of MCFD2, including "normal" MCFD2.

Additionally, the claims broadly encompass detection of variant polypeptides using differential antibody binding. Although the specification teaches that antibodies were generated against full length his-tagged MCFD2, the specification does not teach any antibodies which were able to specifically bind to any of the variant MCFD2 polypeptides.

The state of the prior art and the predictability or unpredictability of the art:

The art of identifying novel MCFD2 variant nucleic acids or polypeptides which are sufficiently correlated with or indicative of F5F8D is highly unpredictable. Knowledge of the sequence of the wildtype MCFD2 gene does not allow one to immediately envision additional mutations that are associated with disease. At the time the invention was filed, the art was silent with regard to MCFD2 function, or F5F8D mutations, other than work published which included the instant inventors and summarized the teachings of the instant specification (Zhang et al; "Zhang I"; Blood, vol 100, No. 11, abstract 1; November 2002)

The specification does not teach a predictable means for identifying additional variations associated with MCFD2 or for distinguishing between variations associated with MCFD2 and naturally occurring polymorphisms. While the specification teaches specific mutations which exhibited diffuse staining patterns in the cell and appeared to be associated with a lack of MCFD2/LMAN1 co-immunoprecipitation, without extensive information regarding the structure-function relationship between MCFD2, LMAN1, and F5F8D, it is highly unpredictable

as to what would be the identity of additional mutant, allelic, or splice variants which would be associated with F5F8D, including those that prevent expression of normal MCFD2 polypeptide. Thus, one cannot readily anticipate the effect of a polymorphism or mutation within the MDFD2 gene.

The level of skill in the art:

The level of skill in the art is deemed to be high.

The quantity of experimentation necessary:

The specification teaches 7 variants in the MCFD2 gene which were found in patients with F5F8D. However, the MCFD2 gene is large, comprising about 23Kb, spanning 4 exons. To identify additional variants of the MCFD2 gene which are associated with F5F8D would require extensive experimentation. For example, such experimentation may involve sequencing the MCFD2 gene of affected individual, sequencing the MCFD2 gene of control individuals which do not have F5F8D or a family history of F5F8D, comparing the sequences of these two groups, and then identifying variations which are present only in the affected group and not in the control group. Such random, trial by error experimentation is considered to be undue. While methods for sequencing genes are known in the art, such methods provide only the general guidelines that allow researchers to randomly search for mutations that may be linked to a disease. The results of performing such methodology is highly unpredictable. The specification has provided only an invitation to experiment. The specification does not provide a predictable means for identifying

additional variants of the MCFD2 gene, which are correlated with or indicative of F5F8D, as is broadly encompassed by the pending claims.

The claims broadly encompass detection of variant polypeptides using differential antibody binding. Neither the prior or postfiling date art, or the specification, teach an antibody that is capable of specifically differentiating the MCFD2 variants or specifically binding to any o the variants set forth in table 1. It is unpredictable whether the amino acid change would be sufficient to result in the production of antibodies that can differentiate between the two molecules. In some cases, an antibody elicited by one antigen can cross-react with a different antigen if the two different antigens share an identical or very similar epitope (Goldsby et al., Immunology; 2003, p. 141). Thus, absent knowledge of the binding epitopes and the effects of the instant polymorphism on those epitopes, it is difficult to predict whether or not any generated antibody will be able to function to differentiate the two alleles in an assay. In the instant case, it is unpredictable as to whether or not an antibody would be able to differentiate between the variants, a feature that is encompassed by the claimed invention.

Case law has established that '(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that '(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art. Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that '(I)t is the specification, not the

knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement".

In the instant case, the claims do not bear a reasonable correlation to the scope of enablement because the specification teaches only 7 mutations within the significantly large MCFD2 gene which are associated with F5F8D. The specification does not teach a representative number of additional variants, including insertions, deletions, substitutions or splice variants, or gross chromosomal rearrangements which are associated with F5F8D. Accordingly, although the level of skill in the art of molecular biology is high, given the lack of disclosure in the specification and in the prior art and the unpredictability of the art, it would require undue experimentation for one of skill in the art to make and use the invention as broadly claimed.

Response to Arguments

7. The response traverses the rejection. The response asserts that the specification fully enables the claims and that the examiner has provided no evidence, law or reasoning regarding the amendment to claim 12 to include "providing a biological sample from a subject suspected of having combined factor 5 and factor 8 deficiency". This argument has been thoroughly reviewed but was found persuasive as the response referenced the enablement rejection and the reasons set forth above. The recitation of a subject suspected of having combined factor 5 and factor 8 deficiency does not enable the claims because the specification does not provide a predictable means for identifying additional variants of the MCFD2 gene, which are correlated with or indicative of F5F8D, as is still broadly encompassed by the pending claims. The response further asserts that the Examiner has provided no evidence, law or reasoning for the

assertion regarding "a representative number of additional variants" and that Applicants were the first to ever to identify alleles of MCFD2 that cause bleeding disorders, that the Specification, Drawings, claims and sequence listing disclose a wide range of splice variants, deletions, frameshifts, truncations, and substitutions with clear cut cause and effect relationships between variants MCFD2 sequences and bleeding disorders and that therefore Applicants are entitled to the claimed genus. This argument has been thoroughly reviewed but was not found persuasive. Although the specification teaches that the D129E mutant and I136T mutant displayed diffuse staining patterns in cells as opposed to wildtype MCFD2 which overlapped with LMAN1 (page 97), The specification does not teach the specific function of MCFD2. Although the specification teaches that in vitro studies found that MCFD2 interacts with LMAN1 in a calcium dependent manner (page 98), other than identifying the specific variants set forth in table 1, the specification does not teach which additional amino acids in MCFD2 would be expected to be associated with F5F8D, nor how any variants, other than the 2 missense mutations, would be expected to alter the function, expression, or activity of MCFD2. The specification does not teach a predictable means for identifying additional variations associated with MCFD2 or for distinguishing between variations associated with MCFD2 and naturally occurring polymorphisms. Without extensive information regarding the structure-function relationship between MCFD2, LMAN1, and F5F8D, it is highly unpredictable as to what would be the identity of additional mutant, allelic, or splice variants which would be associated with F5F8D.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

8. Claims 12-16 and 20-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is maintained for claims 12-16 and 20, and newly presented for newly added claim 21.

The specification defines the recitation of "MCFD2" as a protein or nucleic acid, that in some mutant forms, is correlated with factor V or factor VIII deficiency (F5F8D) (page 9, lines 20-24). Claims 12-16, and 20-21 are drawn broadly drawn to encompass methods for detecting broadly "any" variant MCFD2 polypeptides in a human subject, including any variants which are correlated with or indicative of F5F8D, and diagnosing factor 5 and factor 8 deficiency on the basis of detecting. The claims encompass methods which detect any polypeptide variant or nucleotide variation in the MCFD2 gene which encode a variant MCFD2 polypeptide, including any C-terminal truncation of SEQ ID NO: 2 (claim 13), or "encodes a change in the amino acid sequence of said variant MCFD2 polypeptide" (claim 20), or "prevents expression of normal MCFD2 polypeptide". The claims do not define the identity or position of the polypeptide or nucleotide variation.

The specification teaches 7 mutations that were identified in human patients having F5F8D (see Table 1, page 95: 149+5 G>A, 309+1 G>A, 103delC, 249DelT, 263-270delTTGATGGC, C387>G, and T407>C). Although table 1 references specific SEQ ID NO: with regard to the mutations, the position of these mutations in SEQ ID NOS 1, 2, and 19 is

unclear. The specification does not disclose and fully characterize the genus required by the claims of any variation in the MCFD2 gene in humans, diagnostic of factor 5 and factor 8 deficiency, or which prevent expression of "normal" MCFD2. The specification does not teach the function of MCFD2, accordingly, the disclosure is insufficient to allow the skilled artisan to determine which mutations prevent expression of "normal MCFD2", vs "abnormal" MCFD2.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, 7 members of the genus of MCFD2 nucleotide variations

have been identified. No additional nucleotide variations have been disclosed. It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g. restriction map, biological activity of an encoded protein product, etc.). In the instant case, no such identifying characteristics have been provided for any of allelic variants or mutant MCFD2 nucleic acids or polypeptides. However, the claims as written are inclusive of a potentially large genus of mutations in the MCFD2 gene in humans.

Further, the claims encompass mutations in the MCFD2 gene correlated with or indicative of F5F8D, which represent a distinct group of nucleotide variations which are expected to occur at only specific locations within the gene and consist of specific nucleotide alterations. Accordingly, knowledge of the sequence of the wild-type gene does not allow the skilled artisan to envision all of the contemplated polymorphisms encompassed by the claimed genus. Conception of the claimed invention cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of potential methods for isolating additional nucleotide variations. As stated in *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. LTD*, 25 USPQ2d 1016, one cannot describe what one has not conceived. Additional MCFD2 variants have been taught in the postfiling date art, which have not been taught or described in the instant specification (see "Zhang II"; Zhang et al; Blood, vol. 107, pages 1903-1907, 2006; Table 1: -6-IG>C and D89A).

The genus encompassed by the claims includes an enormous number of polymorphisms and mutations for which no written description is provided in the specification. The disclosure in the specification of 7 mutations MCFD2 gene is not considered to constitute a representative number of nucleotide variants, including insertions, deletions, substitutions or splice variants, in

any exon, intron or non-coding region of MCFD2 or gross chromosomal rearrangements in the MCFD2 which are associated with F5F8D because it is not clear which mutations would have the same affect. No common element or attributes of the sequences are disclosed which would permit selection of sequences as variants. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations of associating a variant with F5F8D is provided.

Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001. In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) In the instant case, the specification fails to teach the necessary common attributes or features of the genus of encompassed polypeptides, nucleic acids and variants in view of the species disclosed. As such, one of skill in the art would not recognize that applicant was in possession of the genus of variants encompassed by the broadly claimed invention.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 recites "normal" MCFD2. However, the specification does not teach the function of MCFD2. Accordingly, the term "normal" is vague and indefinite because the specification fails to define the metes and bounds of the term. This newly presented rejection is necessitated by the claim amendment.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 12-16 and 20-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Zhang I (Zhang et al; Blood, vol 100, No. 11, abstract 1; November 2002).

The rejection is maintained for claims 12-16 and 20, and newly presented for newly added claim 21.

Zhang I teaches detecting variant MCFD2 (CFD2) polypeptides and nucleic acids in a sample from patients with F5F8D. With regard to claim 13 and 21, although Zhang I does not teach that certain mutations resulted in a C terminal truncation or prevented expression of normal MCFD2, as the reference is applicant's own work, the PTO has basis for believing that the reference anticipates the claims. As stated in the MPEP in chapter 2100:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness

has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Response to Arguments

13. The response traverses the rejection and asserts that since the reference is "applicant's own work" the rejection under 35 USC 102(a) is improper. This argument has been thoroughly reviewed but was not found persuasive. As the reference contains an author which is part of the inventive entity, it qualifies as the work of applicant. However, the authorship and the inventive entity are different and qualifies as "known or used by others" and is properly rejected under 35 USC 102(a). See MPEP 2132(III).

Conclusion

14. No claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday, Wednesday and Thursday from 9:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Jehanne Sitton/
Primary Examiner
Art Unit 1634